Plan Overview

A Data Management Plan created using DMPonline

Title: RELOCATE (REpeat LOCal Ablative Treatment for colorectal oligomEtastases)

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Template: UMC Utrecht DMP with DPIA V.3.0

Project abstract:

Throughout the recent years, metastases-directed local therapies (MDTs) including stereotactic body radiotherapy (SBRT) has emerged as an effective, local therapy for treating limited (oligo) metastatic disease. This study presents the characteristics and clinical outcomes of patients diagnosed with repeat oligorecurrent metastatic colorectal cancer (mCRC) who were treated with SBRT. It is of interest to examine the survival of these patients and find potential clinical markers to predict which patients benefit most.

ID: 172506

Start date: 10-03-2025

End date: 31-08-2026

Last modified: 09-12-2025

RELOCATE (REpeat LOCal Ablative Treatment for colorectal oligomEtastases)

1. General features

1.1. Acronym/short study title

RELOCATE (REpeat LOCal Ablative Treatment for colorectal oligomEtastases)

1.2 Division of Principal Investigator

- Beeld & Oncologie (Imaging & Cancer Center)

Principal Investigator: dr. G. M. Bol (medical oncologist, UMCU)

1.3 Department

Department of Medical Oncology

1.4 Path of the Research Folder

\\ds\data\Beeld\ResearchFolders\3_niet-WMO_Coordinerend (naam specifieke studiemap nog te maken)

1.5 WMO/DEC

- non-WMO

1.6 Research type(s)

- Clinical

1.7 Research design(s)

- Retrospective

1.8 Mono or multicenter study (one choice)

- Multicenter

1.9 The role of UMC Utrecht is:

- Initiating / sponsor center

1.10 Which organization is the sponsor of the study?

UMC Utrecht

1.11 Name of datamanager consulted

Rogier Schokker

1.12 Last check date by datamanager

2025-04-10

1.13 Indicate which laws and regulations are applicable for the project (please check all that apply)

- Wet Kwaliteit, klachten en geschillen zorg
- Nederlandse gedragscode wetenschappelijke integriteit
- Gedragscode Gezondheidsonderzoek (Dutch)
- Wet op de Geneeskundige Behandelingsovereenkomst (WGBO) or Medical Treatmants Contracts Act
- Algemene Verordening Gegevensbescherming (AVG) or General Data Protection Regulation (GDPR)

Non-WMO, retrospective research

2. Data Collection

2.1 Give a short description of the research data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Personal data involved?
Human	~150	EPD	Castor	Quantitative	.csv	Yes

2.2 Describe the flow of the data (name systems used and/or third parties, recipients) <add link to location where diagram is stored in RFS>

1. Data source: EPD
2. Data capture tool: Castor
3. Data analysis: R Studio
4. Output: scientific paper, publication

2.3 Estimated storage space for your project

- < 250 GB (e.g. questionnaires, textfiles, datasets)

2.4 Can you reuse existing data? If so, list the data source(s)

- Yes. We use (EPD) data from other hospitals or primary care.
- Yes, in this study, we use data from HiX.

We use data from UMC Utrecht (from HiX), and other hospitals will contribute their data (also from an EPD) to the same Castor database.

2.5 Describe how you will take care of good data quality.

#	Question	Yes	No	N/A
1.	Do you use a GCP-compliant Data Capture Tool or Electronic Lab Notebook?	X		
2.	Have you built in skips and validation checks?	X		
3.	Do you perform repeated measurements?	X		
4.	Are your devices calibrated?			X
5.	Are your data (partially) checked by others (4 eyes principle)?	X		
6.	Are your data fully up to date?	X		
7.	Do you lock your raw data (frozen dataset)	X		
8.	Do you keep a logging (audit trail) of all changes?	X		
9.	Do you have a policy for handling missing data?	TBD		
10.	Do you have a policy for handling outliers?	TBD		

2.6 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Department	Funder	Other (please specify)
1.	Time of datamanager	X			
2.	Design of eCRF	X			
3.	Data Capture Tool license fee				RVB/UMCU
4.	Storage	X			
5.	Archiving	X			

2.7 Please give some more details on other centers and organizations involved. What are the roles of the other centers and organizations involved? (What research activity does this organization carry out in relation to the study and the data?)

Organization	Role/research activity
UMC Utrecht	Sponsor Inclusion of study subjects --> data in CASTOR
Erasmus MC Rotterdam	Inclusion of study subjects --> data in CASTOR
University Hospital Zurich	Inclusion of study subjects --> data in CASTOR
Tübingen University Hospital	Inclusion of study subjects --> data in CASTOR

2.8 Which contracts are in place?

Organization	Contract Type with UMCU	JOIN number
Erasmus MC Rotterdam	DTA	TBD
University Hospital Zurich	DTA	TBD
Tübingen University Hospital	DTA	TBD

2.9 State how ownership of the data and intellectual property rights (IPR) to the data will be managed

UMC Utrecht is and remains the owner of all collected data for this study. The data is collected in a relatively large patient group and is very valuable for further, broader studies in Europe. Our data cannot be protected with IPR, but its value will be taken into account when making our data available to others, when setting up Research Collaborations and when drawing up Data Transfer Agreement(s).

2.10 Use of new technology. Does your study involve the implementation of a technology that has not been used before at UMC Utrecht?

- No

2.12 Will the study need/use personal data (directly or indirectly identifying)? For example, from the Electronic Patient Files (EPD; HiX), DNA, body material, images or any other form of personal data?"

- Yes. You have indicated that you are using personal data in your project. The following chapter is the Data Protection Impact Assessment (DPIA) for research data. It is derived from the full DPIA, in accordance with the privacy office of UMC Utrecht. Answering questions in this chapter helps to determine the risk of processing the personal data and what measures to take to minimize these risks.

3. Data Protection Impact Assessment (DPIA)

3.1 Describe the recipients outside the UMC Utrecht to whom the personal data are provided, what their role is (controller or processor) and where they are located.

- All systems and service providers involved are mentioned in question 2.1 and 2.2. All of them are already contracted by UMC Utrecht. I do not share personal data with other organisations.

3.4 What type of sensitive personal data will be used?

- Health data

3.5 What type of directly or indirectly identifying personal data will be used? Indicate why you need this data. Is this truly necessary?

Category of personal data	Reason for collecting these data
Age (and other demographic data (sex, WHO performance status, tumor characteristics)	To create a baseline table with a description of included patients and their tumor and treatment characteristics.
Details on received treatments and follow-up data (e.g. vital status)	To perform statistical analysis for our research question.

3.6 Select any vulnerable groups from which you will collect data.

- Patients

3.7 Which legally prescribed personal number will be used? Note: it is NOT allowed to use BSN (or its international counterpart) for scientific research purposes.

- None

3.8 Can the purpose of the study be achieved with anonymous or pseudonymized data?

- No, I need direct identifying personal data to answer the Study research question the dataset is stored in folder C_PersonalData of your research folder structure with access only for the persons that need access to this data (explain why you cannot do the research without this data)

Data from the EPD --> to CASTOR, and the patients will be numbered by study ID's (e.g. 001, 002, 003).

3.9 Which measures are taken to prevent the data from being traceable to the natural person? Also consider the measures taken to prevent data breaches.

- Role specific access to identifying data
- Clear retention period(s)
- Parties have ISO27001 and/or NEN7510 certification(s)*
- 2FA/MFA before access to (health) data
- Pseudonymization of data

3.10 Does the reuse of the data fit within the purpose for which they were originally collected?

- No, we will reuse data from the Electronic Health Record (HiX, PACS/RIA, Metavision etc.)

3.11 Are data subjects contacted and included only after informed consent?

- No, we don't ask consent. We will substantiate in the next questions why we cannot ask consent and check whether the data subject has objected (“objection check”).

We will use retrospective data from the EPD, which is pseudonymized in CASTOR. The cohort will include a large number of patients who are deceased or referred to other hospitals, making it difficult to request informed consent. We intend to include patients who were treated up to ten years ago, and contacting all patients or their spokespersons, as well as obtaining their responses, would be an excessive effort.

3.12 What criteria, as formulated in the Dutch Medical Treatment Contracts Act (WGBO) and GDPR, is applicable for not obtaining informed consent?

- Approaching the patient causes a great psychological burden
- It involves a disproportionate amount of effort (a very large number of patients (>500))
- Current contact details cannot be retrieved
- Subjects are deceased

We will use retrospective data from the EPD, which is pseudonymized in CASTOR. The cohort will include a large number of patients who are deceased or referred to other hospitals, making it difficult to request informed consent. We intend to include patients who were treated up to ten years ago, and contacting all patients or their spokespersons, as well as obtaining their responses, would be an excessive effort and could also be a great psychological burden.

3.13 Please explain why above mentioned ground for not obtaining informed consent is applicable for your specific study situation:

We will use retrospective data from the EPD, which is pseudonymized in CASTOR. The cohort will include patients who are deceased or referred to other hospitals, making it difficult to request informed consent. We intend to include patients who were treated up to ten years ago, and contacting all patients or their spokespersons, as well as obtaining their responses, would be an excessive effort

and could also be a great psychological burden.

3.14 Who will perform the objection-check and when?

No-objection check: As these are oncological patients, most have already been consulted by the treating physician regarding participation in the research. If a clear objection is raised, it has been recorded in HiX and reviewed when the data is retrieved for analysis.
Objection check will be done bij datamanagement Imaging and Oncology

3.15 Check if all requirements, additional to the criteria in 3.12 as formulated in the Dutch Medical Treatment Contracts Act (WGBO), GDPR, and Gedragscode Gezondheidsonderzoek, are met:

- The use of patient data for this study will be noted in the patients' medical file
- The study is related to the disease area or areas of the disease
- Asking specific permission is impossible or involves a disproportionate amount of effort
- The study will take measures so that the privacy of the person concerned is not disproportionately harmed
- The study serves a general purpose like public health
- The study cannot be executed without these data
- The patient did not object against the use of his/her data for scientific purposes
- Measures are taken to prevent identification of the data subject

3.17 Is there a dispute settlement or a party where the subject can go to with questions or complaints about the processing of personal data?

- Subjects are informed via the general Privacy Statement.

3.18 Describe how you manage your data to comply to the rights of study participants.

- A subject can object to processing of their personal data or withdraw consent

3.19 Does the data collected concern data from which behavior, presence or performance (profiling) can be measured when this is not the purpose of the research?

- No

3.20 Are automated (i.e. without any human intervention) decisions made about the subjects based on the data?

- No

3.21 Describe the tools, procedures and transport methods that you use to ensure that only authorized people have access to personal data

- Surffilesender --> if yes: encrypted?
- We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID
- We make use of a certified Electronic Data Capture (EDC) tool (Castor), with user roles defined in such a way that user accounts only have access to patients from own center with the necessary role to add, view, edit and export data, except for the sponsor of the study

3.22 Describe your backup strategy or the automated backup strategy of your storage locations.

- All (research) data is stored in the RFS on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
- All (research) data is stored in the RFS on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
- During data collection, automatic backups will be made in the Electronic Data Capture Tool Castor. Upon completion of data collection, all data are exported and saved in the Research Folder Structure where they are automatically backed up by the UMC Utrecht backup system.

3.23 Describe who will have access to which data during your study.

Type of data	Who has access
Direct identifying personal data	Research team under instruction of a physician with a care relationship, Datamanager, PI
Key table linking study specific IDs to Patient IDs	Research team under instruction of a physician with a care relationship, Datamanager
Pseudonymized data	Research team, Datamanager

3.24 Indicate the ISO who was consulted for this DPIA and what advice follows from this?

- Positive (describe further recommendations in text, if applicable)

no findings. Agreed as discussed With ISO Imaging and Oncology

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

For the data collected in Castor, a codebook of my research database is available in Castor.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version and older versions are moved to a folder OLD.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

- It is anticipated that we are going to write a paper and publish it, which will make the research

accessible to peers.
- I will make an overview of datasets and analysis scripts, such that it is fully clear how the statistical analysis is performed. Peers will be able to repeat the analysis based on my overview.
- We will be using tools like SAS, R or SPSS for statistical analysis of the data. The scripts will contain comments, such that every step in the analysis is documented and peers can read why I made certain decisions during the analysis phase.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw data, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, and a ‘read me.txt’ file with an overview of files included and their content and use.

7.2 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

- After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. The (meta)data will be published in DataverseNL, the preferred UMCU repository.

7.3 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

- I will be using a DOI-code and will update this plan as soon as I have the code. The DOI-code can then be found in the additional comment area of this plan.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

The raw data can be of interest for other researchers or for spin off projects.

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict

access to the data once made publicly available?

- Yes (please specify)

As the data is privacy-sensitive, we publish the descriptive metadata in the data repository with a description of how a data request can be made (by sending an email to the corresponding author). In the event that peers like to reuse our data this can only be granted if the research question is in line with the original informed consent signed by the study participants. Every application therefore will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

(Meta)data will be available upon request after the article is published.

8.5 Describe where you will make your data findable and available to others.

We will follow the UMC Utrecht guidelines for publishing research data. On Dataverse, the contact details of the PI will be published for possible data requests.